CLAIMS

1. A process for purification of optically impure Ramipril to obtain Ramipril(I) having optical purity of at least 99.9 %, which comprises crystallizing optically impure Ramipril from an organic solvent.

2. The process as claimed in claim 1 wherein the organic solvent is, an aliphatic esters, an acetal, a nitroalkane or a mixture thereof.

3. The process as claimed in claim 1 wherein the organic solvent is selected from methyl formate, nitromethane, dimethoxymethane, diethoxymethane, and 2,2, - dimethoxy propane and mixture thereof.

4. The process as claimed in claim 1 wherein the organic solvent is diethoxymethane.

5. A monohydrate of Ramipril(I), having an X-ray powder diffraction pattern with characteristic peaks (2θ): 8.7, 9.2, 9.4, 9.7, 11.2, 11.6, 12.2, 14.54, 15.7, 18.0, 19.7, 24.5 and 24.8.

6. The Ramipril(I) monohydrate as claimed in claim 5 having an X-ray diffractogram, or substantially the same X-ray diffractogram, as set out in Figure 1a.

7. The Ramipril(I) monohydrate as claimed in claim 5 having DSC thermogram as described in Fig. 1c.

8. The Ramipril(I) monohydrate as claimed in claim 5 having TGA thermogram as described in Fig. 1d.

9. A process for preparation of Ramipril(I) monohydrate comprising of, crystallizing optically impure Ramipril from a mixture of water and water-immiscible solvents.

10. The process claimed in claim 9 wherein the ratio of water-immiscible solvent to water is in the range from 2 to 98% w/w.

11. The process as claimed in claim 11 wherein the said water-immiscible solvent is selected from an aliphatic ester, an acetal, a hydrocarbon or a mixture thereof.

12. The process as claimed in claim 11 wherein the said water-immiscible solvent is selected from diisopropyl ether, diethoxymethane, 2,2-dimethoxy propane, cyclohexane, methyl isobutyl ketone and ethyl acetate or a mixture thereof.

13. A process for preparation of Ramipril(I) monohydrate comprising of, crystallizing optically pure Ramipril(I) from water.

14. A process for the preparation of anhydrous form of Ramipril(I) from Ramipril(I) monohydrate comprising heating of Ramipril(I) monohydrate at a temperature in the range from 40 °C to 42 °C under reduced pressure in the range from 2 mm hg to 5 mm hg.

15. A pharmaceutical composition comprising an effective ACE inhibitory amount of Ramipril(I) monohydrate as claimed in any preceding claims, together with one or more pharmaceutically acceptable carriers, diluents or excipients thereof.